PATENT

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Applicant:	HAEFNER	Examiner:	Kahelin, M.
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Title:	HEART SOUNDS FOR SELECTION OF SEPARATED SIGNALS		

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REPLY BRIEF

Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a Reply Brief submitted pursuant to 37 C.F.R. § 41.37(c)(1)(vii) for the above-referenced patent application. No charges are believed due for the filing of this Reply Brief. However, if necessary, authority is given to charge/credit deposit account 50-3581 (GUID.606PA) any additional fees/overages in support of this filing, as indicated in 37 C.F.R. § 41.20(b)(2).

Per 37 C.F.R. § 41.39(b)(2), this Reply Brief contains the formalities of 37 C.F.R. § 41.37(c) because the Examiner's Answer contained a new grounds of rejection. This Reply Brief is not a substitute brief that replaces the original Appeal Brief filed March 28, 2008. Rather, this Reply Brief supplements the documents filed on appeal.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardiac Pacemakers, Inc.

II. RELATED APPEALS AND INTERFERENCES

Appellant notes that a Notice of Appeal was filed on August 6, 2007, and that a Panel Decision from Pre-Appeal Brief Review to proceed to the Board of Patent Appeals and Interferences was issued on September 25, 2007 for Application Serial No. 11/125,020 (GUID.164PA; 03-175), which also concerns source separation methodologies.

Appellant notes that a Notice of Appeal was filed on August 6, 2007, and that a Panel Decision from Pre-Appeal Brief Review to proceed to the Board of Patent Appeals and Interferences was issued on September 25, 2007 for Application Serial No. 10/955,397 (GUID.183PA; 03-203D), which also concerns source separation methodologies.

Appellant notes that a Notice of Appeal was filed on October 9, 2007, and that a Panel Decision from Pre-Appeal Brief Review to proceed to the Board of Patent Appeals and Interferences was issued on November 7, 2007 for Application Serial No. 11/124,950 (GUID.181PA; 04-055AR), which also concerns source separation methodologies.

III. STATUS OF CLAIMS

Claims 1-19 and 30-36 remain pending. Each of the pending Claims 1-19 and 30-36 has been finally rejected by the Examiner's action dated October 10, 2007, from which Appellant appeals. The pending Claims 1-19 and 30-36 under appeal may be found in the attached Claims Appendix.

IV. STATUS OF AMENDMENTS

No amendments have been presented subsequent to the final rejection dated October 10, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates generally to implantable medical devices and, more particularly, to subcutaneous cardiac sensing and/or stimulation devices employing cardiac signal separation.

Some method embodiments of the present invention are directed to signal separation. (*See, e.g.*, Claim 1, Page 4, Line 27 – Page 5, Line 14, among other locations). Such methods can include detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources. (*See, e.g.*, Page 8, Line 19 –Page 16, Line 22; Page 22, Lines 22-24; Page 24, Lines 7-25; Page 31, Lines 17-27; among other locations). Such method embodiments may further include receiving information associated with a non-electrophysiological cardiac source. (*See, e.g.*, Page 17, Line 26 – Page 18, Line 28; Page 20, Line 8 – Page 21, Line 15; Page 22, Line 25 – Page 23, Line 7; Page 30, Line 10 – Page 31, Line 16; among other locations). Such method embodiments may further include separating a signal from the composite electrical signal using source separation. (*See, e.g.*, Page 25, Line 24 – Page 28, Line 9; Page 28, Line 19 – Page 29, Line 7; among other locations). Such method embodiments may further include verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. (*See, e.g.*, Page 25, Lines 22-24; Page 26, Line 27 – Page 27, Line 6; Page 29, Line 8 – Page 30, Line 9; Page 32, Line – Page 34, Line 22; among other locations).

Such method embodiments may further include that verifying that the separated signal is the cardiac signal comprises providing a detection window defined by a start time and a stop time determined using the non-electrophysiological cardiac source information. (*See, e.g.*, Claim 2; Page 5, Lines 6-14; Page 29, Lines 18-21; Page 30, Lines 17-27; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Such method embodiments may further include detecting a QRS complex within the detection window. (*See, e.g.*, Claim 3; Page 5, Lines 6-14; Page 29, Lines 18-21; Page 30, Lines 17-27; Page 32, Lines 1-5; Page 32, Line 19 – Page 34, Line 17; among other locations).

Such method embodiments may further include that verifying that the separated signal is the cardiac signal comprises providing a detection window defined by a start time

preceding the temporal location of a peak heart-sound. (*See, e.g.*, Claim 6; Page 5, Lines 6-14; Page 29, Lines 18-21; Page 30, Lines 17-27; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Such method embodiments may further include that verifying that the separated signal is the cardiac signal comprises providing a detection window within which the cardiac signal is correlated to a signal associated with the non-electrophysiological cardiac source. (*See, e.g.*, Claim 11, Page 5, Lines 6-14; Page 29, Lines 18-21; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Such method embodiments may further comprise determining a time separation between a peak of the separated signal and a peak of a signal associated with the non-electrophysiological cardiac source. (*See, e.g.*, Claim 12, Page 5, Lines 6-14; Page 29, Lines 18-21; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Such method embodiments may further include that the time separation is used to identify a cardiac signal. (*See, e.g.*, Claim 13, Page 5, Lines 6-14; Page 29, Lines 18-21; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Such method embodiments may further comprise detecting a cardiac condition using the separated signal by performing a correlation between the separated signal and a signal associated with the non-electrophysiological cardiac source. (*See, e.g.*, Claim 17, Page 5, Lines 6-14; Page 29, Lines 18-21; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; among other locations).

Embodiments can be directed to an implantable cardiac device. (*See, e.g.*, Claim 30; Page 8, Line 10 – Page 9, Line 8; Page 19, Lines 12-22; Page 22, Line 6-13; Page 24, Lines 3-6; elements 102, 501, 205, 206, 209, 220, 218, 216, 230, 214, 207, as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations). Such embodiments may include means for subcutaneously detecting a composite electrical signal associated with a plurality of signal sources. (*See, e.g.*, Page 8, Line 19 – Page 16, Line 2; Page 15, Line 13 – Page 16, Line 22; Page 22, Lines 22-24; Page 24, Lines 7-25; Page 31, Lines 17-27; elements 104, 106,202, 207, 214, 204, 203, 504, 506, 502, as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations). Such embodiments may include means for subcutaneously detecting non-electrical cardiac activity. (*See, e.g.*, Page

17, Line 26 – Page 18, Line 28; Page 20, Line 8 – Page 21, Line 15; Page 22, Line 25 – Page 23, Line 7; Page 30, Line 10 – Page 31, Line 16; elements 261, 204, 203, 202, 316, 318, 502, 504, 104, 106, 214, 207, as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations). Such embodiments may include means for separating a signal from the composite electrical signal using source separation. (*See, e.g.*, Page 25, Line 24 – Page 28, Line 9; Page 28, Line 19 – Page 29, Line 7; 204, 203, 210, 202, 205, 206, 209, 314, 316, 318, 302, 306, 310, 312, as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations). Such embodiments may include means for determining whether or not the separated signal is a cardiac electrical signal using the detected non-electrical cardiac activity. (*See, e.g.*, Page 25, Lines 22-24; Page 26, Line 27 – Page 27, Line 6; Page 29, Line 8 – Page 30, Line 9; Page 32, Line – Page 34, Line 22; as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations).

Such embodiments may further include that determining means comprises means for performing a time correlation between the separated signal and a signal associated with the detected non-electrical cardiac activity. (*See, e.g.*, Claim 31, Page 29, Lines 18-21; Page 32, Lines 1-5; Page 32, Line 21 – Page 34, Line 17; as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations).

Such embodiments may further include that determining means comprises means for means for evaluating the separated signal within a detection window. (*See, e.g.*, Claim 32, Page 5, Lines 6-14; Page 29, Lines 18-21; Page 30, Lines 17-27; Page 32, Line 1 – Page 34, Line 17; as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations).

Such embodiments may further include means for determining a start time to initiate the detection window. (*See, e.g.*, Claim 33, Page 5, Lines 6-14; Page 29, Lines 18-21; Page 30, Lines 17-27; Page 32, Line 1 – Page 34, Line 17; as well as the descriptions in the specification of the identified elements and elements described in the cited passages, among other locations).

Appellant notes that a single structure may correspond to multiple "means" limitations. (*See, e.g., Winbond Electronics Corp. v. International Trade Commission*, 4 Fed.Appx. 832, C.A.Fed., 2001). Further, means recited in a dependent claim can use the means of an earlier referenced claim. For example, the means referenced in dependent claim 33 can use the means listed in association with independent claim 30.

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein. Appellant notes that representative subject matter is identified for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Appellant thus submits that other application subject matter, which supports the claims but is not specifically identified above, may be found elsewhere in the application. Appellant further notes that this summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36 stand rejected based on 35 U.S.C. §102(b) as being anticipated by U.S. Re. No. 30,750 to *Diack et al.*

B. Claims 1-19 and 30-36 stand rejected based on 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,388,578 to *Yomtov et al.* in view of U.S. Publication No. 2005/0240234 by *Joo et al.*

C. Claims 14 and 15 stand rejected based on 35 U.S.C. §103(a) as being unpatentable over *Yomtov* in view of *Joo*, as applied to Claim 1, and further in view of U.S. Publication No. 2003/0032889 by *Wells*.

D. Claims 1-13, 16-19, and 30-36 stand rejected based on 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2005/0240234 by *Joo et al.* in view of U.S. Patent No. 5,388,578 to *Yomtov et al.*

VII. ARGUMENT

A. Rebuttal of the Examiner's Response to Argument regarding the 35 U.S.C. §102(b) rejection based on Diack of Claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36.

1. Independent Claims 1 and 30.

The Examiner's rejection ignores how an ordinarily skilled artisan would recognize the claimed source separation methodology in light of the Specification, and interprets the claims solely in a descriptive sense. Even so, using only the descriptive sense of the claimed separating a signal from a composite electrical signal using source separation, the ordinarily skilled artisan would not interpret *Diack's* band pass filtering to meet the claims.

Diack's band pass filtering is performed on the basis of frequency and is not done according to source. The Examiner's "Response to Argument" admits that *Diack's* filtering is performed on the basis of frequency. (Page 15). The Examiner then argues that the filtering frequencies are chosen according to "desired frequency" source and "undesired frequency" source. (Id.).

Regardless of what is desired, *Diack's* filtering based on frequency would necessarily filter content from all sources, desired and undesired, as long as the frequencies were outside of the pass band, and would pass content from desired and undesired sources as long as the frequencies were inside of the pass band. Such frequency based filtering is agnostic to source. One having ordinary skill in the art, ignoring the specification, and searching for correspondence to source separation in only the descriptive sense, would not then conclude that *Diack's* filtering out desired source content and undesired source content (while also keeping desired source content and undesired source content) constitutes separating according to sources.

The Examiner's Response to Arguments further states "The Examiner is of the position that reduction of external interference is still source separation because the desired signal is discerned from the undesired noise." (Page 15). Being that the Examiner is interpreting the claimed "separating a signal from the composite electrical signal using source separation" in only the descriptive sense, the ordinarily skill artisan would not conclude that "reduction of external interferences" constitutes separating a signal from a

composite signal, as in the descriptive sense there is a difference between separating a signal from a composite signal and reducing the signal (or other signals) within the composite signal.

Therefore, in the manner the Examiner states the claims are being interpreted, *Diack* does not teach each claimed element, and therefore cannot anticipate at least independent claims 1 and 30.

Appellant previously argued that *Diack* does not provide correspondence to the claimed step of verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, in the particular manner recited in each of claims 1 and 30. The Response to Arguments section of the Examiner's Answer states that "the Examiner is interpreting the verifying step to be verifying that the signal is an abnormal cardiac signal or normal cardiac signal." (Page 15). However, such an interpretation of the claims is incorrect because the independent claims do not concern verifying that the signal is an abnormal cardiac signal or normal cardiac signal.

If the Examiner is interpreting the verify step to constitute deciding whether a separated signal is an abnormal cardiac signal or normal cardiac signal, then such a step already assumes that the signal is a cardiac signal (and just questions what type of cardiac content is in the signal). The claims, however, concern verifying that the separated signal is a cardiac signal, which is distinguishable from the Examiner's construction which just assumes that the signal is a cardiac signal and tries to decide what type of cardiac signal it is.

Diack uses both sensed EKG signals and respiration sounds to select an appropriate therapy from several therapy options. (See Table 1 in the Figures (next to Figs. 4-6), as cited on Page 2 of the Office Action mailed 10/26/2007). These signals are not used to verify each other as cardiac signals, as *Diack* merely assumes that they are cardiac signals. Therefore, *Diack* does not teach verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. Consequently, the rejection does not account for all elements of independent claims 1 and 30.

For each of the reasons discussed above, there is an omission of at least one essential element required for a proper anticipation rejection of independent Claims 1 and 30 and its

associated dependent Claims 4, 7, 8, 10 16-19, 31, and 34-36, and the anticipation rejection of these Claims should be reversed at least on that basis.

2. Dependent Claims 17 and 31.

Regarding dependent Claims 17 and 31, the Response to Arguments section of the Examiner's Answer states that:

> the signals are "time-correlated" because they are compared simultaneously. As electrical activity is ascertained at the same time as sound, the signals are correlated in time at the time of comparison/verification. (Page 16).

Appellant respectfully submits that the subject matter of Claims 17 and 31 does not merely concern whether the data was collected contemporaneously.

For example, Appellant's Claim 17 recites detecting a cardiac condition using the separated signal by performing a correlation between the separated signal and a signal associated with the non-electrophysiological cardiac source. Appellant's Claim 31 depends from independent Claim 30, and further recites means for performing a time correlation between the separated signal and a signal associated with the detected non-electrical cardiac activity.

The correlation is claimed as a separate step ("performing a correlation between . . ."). Even if *Diack's* two sets of data are taken at the same time, *Diack* does not disclose the affirmative step of correlating aspects of these data sets with each other (e.g., the performance of a step drawing correlation between the data sets). Hypothetically, someone could think that two data sets correspond in time, but would not know their actual relationship unless a correlation is performed. As such, even if *Diack* collects two data sets at the same time, this does not constitute the affirmative step of performing a correlation between the separated signal and a signal associated with the non-electrophysiological cardiac source, in the manner claimed in claims 17 and 31. Therefore, the rejection fails to

account for all elements of claims 17 and 31 and the anticipation rejection of these claims should be withdrawn.

B. Rebuttal of the Examiner's Response to Argument regarding the 35 U.S.C. §103(a) rejection based on Yomtov and Joo of Claims 1-19 and 30-36.

1. Independent Claims 1 and 30.

The Examiner interprets the claimed step of separating a signal from a composite electrical signal using source separation not in the sense the ordinarily skilled artisan would interpret such terms in light of the Specification, but rather only in the descriptive sense of the words. Using this interpretation, the Response to Arguments of the Examiner's Answer states:

> The R-wave detector separates the R-wave source form [sic] the other ECG features (such as P, Q, S, and T waves), and further, paced pulses come from the stimulator source and paced beats come from myocardial tissue. Although Yomtov does not disclose the phrase "source separation," the Examiner maintains that this separation of the R-wave from the other features of the ECG reads on the claim language. (Page 16).

A PQRST complex represents the classic electrical cycle of a heart as read by an ECG, each letter referring to a different feature, as shown by Fig. 2 of *Yomtov* below:

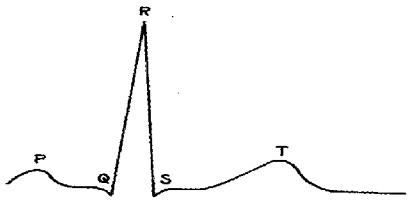


FIG. 2

All of the lettered features correspond to different electrical events of the heart throughout the heart beat cycle. If the R-wave is in some sense separated or distinguished from the other lettered features, all lettered features of the signal still have the common origin: the heart. Using the Examiner's interpretation of the claims and *Yomtov*, it would

seem that the distinguished signal content still comes from the same source (the heart), and therefore is not source separation.

The Examiner as argued, as quoted above, that *Yomtov* separates paced beats from natural beats, and argues that these are different sources (the pacemaker being the other source). However, Appellant notes that the PQRST complex is generated by heart activity regardless of whether the heart beat was paced or natural. The heart still generates electricity and gives off the ECG electrical signature whether paced or natural (the pacemaker just makes sure this process gets started – it sets the pace). Therefore, when *Yomtov* detects R-waves, these R-waves come from the heart (and not a pacemaker) whether the particular beat cycle was initiated by a pacemaker or was initiated naturally.

As such, the proffered interpretation of *Yomtov* used to support the rejection of Claims 1 and 30 does not correspond to the claimed elements in any way that one having ordinary skill in the art would interpret *Yomtov* and the claimed elements (e.g., separating a signal from the composite electrical signal using source separation in the manner of claim 1 and 30), and consequently the rejection fails to account for all elements of claims 1 and 30.

The Response to Arguments of the Examiner's Answer further states that:

> Appellant further argued that Yomtov lacks disclosure of verifying that a separated signal is a cardiac signal, but merely switches channels because of noise. The Examiner maintains that Yomtov's disclosure at Col. 17, lines 40-48 provides this teaching because the second channel is utilized to confirm whether the first channel's cardiac signal is valid. (Page 16).

The cited Col. 17, Lines 40-48 of *Yomtov* states:

> In performing step 178 to determine if a valid beat had been detected, the microprocessor utilizes the following criteria. If both the first and second channels contained noise, the microprocessor will determine that a reliable beat classification cannot be performed. If the microprocessor detected that there was noise in one channel and was unable to verify a detected QRS

> complex in the other channel, it will determine that a valid beat had not been detected. As a result, if in step 178 the microprocessor determines that a valid beat had not been detected, it will set in step 182 another refractory period of, for example, 80 milliseconds.

Appellant respectfully submits that the above passage concerns conditions under which signals will not be verified. The actual verification is performed, as discussed previously in Section VII(B) of the Appeal Brief, independently for each signal using zero crossings and thresholds, not a different signal. For example, Col. 16, Lines 61-68 of *Yomtov* discusses the method used in Figs. 8A-B for verifying that a heart beat was detected:

> For example, the microprocessor 92 analyzes the stored data for zero crossings at times which correspond to the ST segment of the ECG wherein, if the heart beat is a valid heart beat, the data would indicate a generally constant level. However, if there was noise in the first channel, the microprocessor will detect zero crossings resulting from signals of changing directions which would not normally occur during this interval. (Col. 16, Lines 61-68).

Accordingly, *Yomtov* discloses independently verifying that data collected on a particular channel is a heart beat by tracking zero crossings and using thresholds, not using one channel to verify that the other channel comprises a cardiac signal. Furthermore, Col. 17, Lines 40-48 of *Yomtov* cited by the Examiner concerns conditions under which such independent verification will not occur, as discussed above.

Therefore, Appellant respectfully submits that the Examiner's construction of *Yomtov* and *Joo* does not teach or suggest verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, as recited in independent claims 1 and 30, and that the rejection consequently does not account for all elements of these claims.

2. Dependent Claim 6.

Appellant's Claim 6 depends from independent Claim 1, and further recites that verifying that the separated signal is the cardiac signal comprises providing a detection window defined by a start time preceding the temporal location of a peak heart-sound.

In addressing this claim, The Response to Arguments section of the Examiner's Answer states that:

> the claim language does not require an actual determination of a peak heart sound, only that the window has a start time preceding the peak heart sound. As the heart sound is a mechanical manifestation resulting from the electrical activity of the ECG, Yomtov inherently meets this limitation (Pages 16-17).

Appellant notes that this is an entirely new interpretation of this claim on appeal, as the Examiner had previously tried to address this claim by acknowledging that *Yomtov* does not address non-electrophysiological signals as the second cardiac source signal and relying on *Joo* to provide this disclosure (Page 3 of the Office Action mailed 10/26/2007).

Even so, Appellant submits that such an interpretation is unreasonable and not one an ordinarily skilled artisan would give to the claims, as such an interpretation would render superfluous most of the claim language (or at least the portion reciting "defined by a start time preceding the temporal location of a peak heart-sound"). (See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)(citing *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004)) regarding proper claim interpretation being reasonable and consistent with the interpretation of an ordinarily skilled artisan; see also MPEP § 2111).

An ordinarily skilled artisan would reasonably interpret claim language to impart some meaning, which is stripped away by the Examiner's unreasonable claim interpretation. When given due meaning, *Yomtov* and *Joo* does not provide for a detection window defined by a start time preceding the temporal location of a peak heart-sound.

Moreover, the claim states that the detection window is defined by a start time preceding the temporal location of a peak heart-sound. As such, identifying the temporal

location of a peak heart-sound is clearly a prerequisite to being able to define the detection window, as the detection window start time is defined by the temporal location of the peak heart-sound. Such a step is not inherent and not addressed by the rejection.

3. Dependent Claims 11 and 17.

In addressing claims 11 and 17, the Response to Arguments section of the Examiner's Answer states that "Joo is relied upon for the teaching of a cardiac and non-electrophysiological signal, and Yomtov is provided for the teaching of correlating two signals in the time window." (Page 17). However, no citations are provided to evidence what subject matter of each of *Joo* and *Yomtov* is being asserted. The rejection of claim 17 on Page 12 of the Examiner's Answer only refers to *Yomtov*.

Moreover, the rejection merely lists concepts and lacks reasoning supported by citation to the cited references. As shown above, no effort is made to explain how the alleged teachings are combined to constitute a proper §103(a) rejection.

The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (*In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385, 1396 (2007) (quoting Federal Circuit statement with approval and stating the reasons for an obviousness type rejection must be made explicit); and MPEP §2141).

Accordingly, the rejection of claims 11 and 17 is unsupported by analysis and evidence, and is consequently improper.

4. Dependent Claims 12 and 13.

Appellant's Claim 12 depends from independent Claim 1, and further recites determining a time separation between a peak of the separated signal and a peak of a signal associated with the non-electrophysiological cardiac source. Appellant's Claim 13 depends

from intermediary Claim 12, and further recites that the time separation is used to identify a cardiac signal.

In addressing these claims, the Response to Arguments section of the Examiner's Answer states that "the Examiner maintains that retrieving a time separation from memory is 'determining a time separation.' Joo is relied upon for the teaching of utilizing a cardiac and non-electrophysiological source." (Page 17).

A retrieved "constant delay stored in memory" (Col. 15, Line 29 of Yomtov cited on page 4 of the Office Action mailed 10/26/2007 addressing these claims) does not constitute determining a time separation between a peak of the separated signal and a peak of a signal associated with the non-electrophysiological cardiac source. Even if the constant delay is stored in memory in *Yomtov*, it is unclear what this delay is between, and how this delay is determined. It would not appear that this delay is determined based on a time separation between a peak of the separated signal and a peak of a signal associated with the non-electrophysiological cardiac source.

As such, not all elements of claims 12 and 13 are addressed by the rejection and the rejection is consequently improper.

C. The rejection under 35 U.S.C. §103(a) of Claims 14 and 15 is improper because Yomtov fails to teach or suggest each of the claimed limitations, even in view of Joo and Wells.

No comment regarding this rejection was provided in the Response to Arguments section of the Examiner's Answer.

D. The new ground of rejection under 35 U.S.C. §103(a) of Claims 1-13, 16-19, and 30-36 is improper because Joo fails to teach or suggest each of the claimed limitations, even in view of Yomtov.

1. Independent Claims 1 and 30.

Claims 1-13, 16-19, and 30-36 are subject to a new rejection based on 35 U.S.C. §103(a) as being unpatentable over *Joo* in view of *Yomtov*.

Appellant's independent Claims 1 and 30 each recite, among other features, some variation of detecting a composite electrical signal at a subcutaneous non-intrathoracic

location, the composite electrical signal associated with a plurality of sources, receiving information associated with a non-electrophysiological cardiac source, and separating a signal from the composite electrical signal using source separation.

In addressing these elements, the Examiner's Answer cites paragraph [0059] and elements 246 and 250 of Fig. 14. (Pages 12-13). Paragraph [0059] of *Joo* recites:

> The defibrillation electrodes 30 may further be used to sense the patient's electrocardiogram (ECG) signals. ECG signals obtained from the patient are amplified by the ECG signal amplifier 52 and filtered by the ECG bandpass filter 54 in a conventional manner. The A/D converter 36 converts the ECG signals into digitized ECG data and provides the ECG data to the processing circuit 38 for evaluation.

It would appear that the Examiner considers band pass filtering "in a conventional manner" to constitute separating a signal from the composite electrical signal using source separation. The Applicant disagrees with this interpretation for each of the reasons discussed in connection with the band pass filtering based rejection using the *Diack* reference. (See Section VII(A) of the Appeal Brief and further discussed in Section VII(A) herein).

For example, one having ordinary skill in the art, viewing Appellant's specification, would readily recognize the differences between source separation methodologies and band pass filtering.

Signal *source* separation of a composite signal involves separating a signal from the composite signal according to the *source* of the signal. (*See* Page 26, Line 27 – Page 27, Line 4 of Appellant's Specification). None of *Joo's* band pass filtering methods contemplate separating a signal from a composite signal according to the source of the signal consistent with source separation, and none of *Joo's* methods involve source separation in a way that this technique is recognized by one having ordinary skill in the art.

Moreover, even if the ordinarily skilled artisan was to ignore the Specification and interpret the claims in a strictly descriptive sense, the ordinary skilled artisan would recognize that conventional band pass filtering is performed according to signal frequency

and is agnostic as to signal source, such that band pass filtering does not separate on the basis of source.

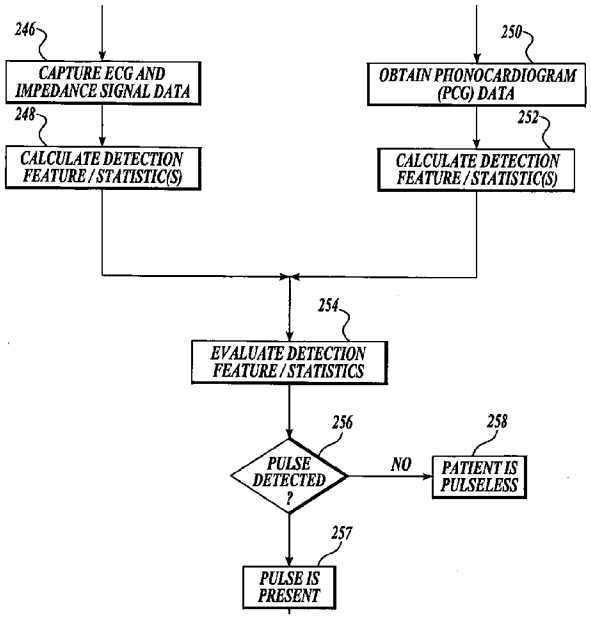
Furthermore, in the cited paragraph [0059], *Joo* merely states that an ECG signal can be filtered using band pass filtering in a conventional manner. *Joo* does not state what content is filtered out of the ECG signal. In particular, *Joo* is silent as to whether the filtering is directed to suppress cardiac or non-cardiac signals, such that no correspondence to source separation can be discerned even in the descriptive sense. Therefore, one having ordinary skill in the art in view of the Specification would not conclude that *Joo's* "ECG signals obtained from the patient are amplified by the ECG signal amplifier 52 and filtered by the ECG bandpass filter 54 in a conventional manner" constitutes separating a signal from the composite electrical signal using source separation, as claimed in independent claims 1 and 30.

Therefore, Appellant respectfully submits that the Examiner's rejection based on *Joo* in combination with *Yomtov* fails to account for all claim elements and is consequently improper.

Appellant's independent Claims 1 and 30 each further recite, among other features, some variation of verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

In addressing these elements, the new rejection in the Examiner's Answer only states that *Joo* discloses "verifying that the separated signal is a cardiac signal by correlating the separated and non-electrophysiological source information (element 256)." (Page 13).

The rejection never explains how Element 256 (found in Fig. 14) constitutes verifying that a separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information. A portion of Fig. 14 is reproduced below:



Paragraphs [0135-0136] discuss Element 256. These paragraphs are directed to determining whether a pulse was detected by either of an ECG, impedance signal, or phonocardiogram. Even through paragraph [0136] states that a "combination of two or more analyzed physiological signals may advantageously provide a more robust pulse detection process with improved detection characteristics," *Joo* does not use one of the signals to verify that a separated signal is a cardiac signal.

Joo does not ask "PULSE DETECTED?" in element 256 because a separated signal needs to be compared to a non-electrophysiological source to verify that it has cardiac content and that a source separation was successful. Rather, the method of Fig. 14 is directed to determining whether to deliver an electrical cardiac therapy, such as when severe heart trouble is indicated by a pulse not being detected. (see last sentence of [0135]). The method of Fig. 14 looks at multiple physiological parameters (ECG, phonocardiogram) to see whether there is any evidence of the heart beating (element 256) to direct subsequent therapy. ([0135]). In *Joo*, an alternative signal is simply not used to verify that the conventionally filtered ECG is a cardiac signal.

For each of the reasons discussed above, Appellant respectfully submits that the Examiner's rejection based on *Joo* in combination with *Yomtov* fails to account for claim recitations of separating a signal from the composite electrical signal and verifying that the separated signal is a cardiac signal using the separated signal and the non-

electrophysiological cardiac source information, as recited in some variation in each of independent Claims 1 and 30.

Consequently there is an omission of at least one essential element required for a proper §103(a) rejection of independent Claims 1 and 30. Dependent Claims 2-13, 16-19, and 31-36 are also patentable over *Joo* in view of *Yomtov*, as each of these Claims respectively depends from one of independent Claims 1 and 30.

2. Dependent Claims 2, 11, 32, and 33.

Appellant's Claim 2 depends from independent Claim 1, and further recites that verifying that the separated signal is the cardiac signal comprises providing a detection window defined by a start time and a stop time determined using the non-electrophysiological cardiac source information.

Appellant's Claim 11 depends from independent Claim 1, and further recites that verifying that the separated signal is the cardiac signal comprises providing a detection window within which the cardiac signal is correlated to a signal associated with the non-electrophysiological cardiac source.

Appellant's Claim 32 depends from independent Claim 30, and further recites that the determining means comprises means for evaluating the separated signal within a detection window. Appellant's Claim 33 depends from independent Claim 32, and further recites means for determining a start time to initiate the detection window.

Regarding these claims, the new rejection in the Examiner's Answer only states that "In regards to claims 2, 11, 32, and 33, the verification step is performed over a detection window defined by a start and stop time determined with the non-electrophysiological signal (par. 0125-0126)." (Page 13). Appellant respectfully disagrees.

One having ordinary skill in the art viewing Appellant's Specification would recognize what it means to initiate a detection window, define a detection window, or otherwise provide a detection window in response to some event. The rejection does not account for the claimed elements because the cited evidence (paragraphs [0125-0126]) do not mention a detection window, and certainly not when to initiate, or how to define, a detection window. Moreover, if signal reception and analysis is generally always occurring, then such

methods would be different from initiating a discrete detection window or defining the terms of the detection window, considering that the term "window" invokes detection boundaries.

For this further reason, the §103(a) rejection of dependent Claims 2, 11, 32, and 33 does not account for all elements, is unsupported, and should be reversed.

3. Dependent Claims 17 and 31.

Appellant's Claim 17 depends from independent Claim 1, and further recites detecting a cardiac condition using the separated signal by performing a correlation between the separated signal and a signal associated with the non-electrophysiological cardiac source. Appellant's Claim 31 depends from independent claim 30, and further recites that the determining means comprises means for performing a time correlation between the separated signal and a signal associated with the detected non-electrical cardiac activity.

Regarding performing a correlation and these claims, the new rejection in the Examiner's Answer only states that *Joo* discloses "verifying that the separated signal is a cardiac signal by correlating the separated and non-electrophysiological source information (element 256)." (Page 13).

The rejection never explains how Element 256 (found in Fig. 14) constitutes performing a correlation between the separated signal and a signal associated with the non-electrophysiological cardiac source. Multiple types of data are independently used in element 256 to provide redundancy and create a more robust detection system. (Last sentence of [0136]). Element 256 does not disclose the affirmative step of performing a time correlation between a separated signal and a signal associated with detected non-electrical cardiac activity, and the rejection is silent as to how such a time correlation would be performed in element 256.

For this further reason, the §103(a) rejection of dependent Claims 17 and 31 does not account for all elements, is unsupported, and should be reversed.

CONCLUSION

In view of the above, Appellant respectfully submits that the claimed invention is patentable over the cited reference and that the rejections of Claims 1-19 and 30-36 should be reversed. Appellant respectfully requests reversal of the rejection as applied to the appealed Claims and allowance of the entire application.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. A signal separation method, comprising:

detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources;

receiving information associated with a non-electrophysiological cardiac source;

separating a signal from the composite electrical signal using source separation; and

verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

2. The method of claim 1, wherein verifying that the separated signal is the cardiac signal comprises providing a detection window defined by a start time and a stop time determined using the non-electrophysiological cardiac source information.

3. The method of claim 2, further comprising detecting a QRS complex within the detection window.

4. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises acoustic emission information.

5. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises a temporal location of a peak heart-sound.

6. The method of claim 5, wherein verifying that the separated signal is the cardiac signal comprises providing a detection window defined by a start time preceding the temporal location of a peak heart-sound.

7. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises blood-flow information.

8. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises pulse pressure information.

9. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises pulse oximetry information.

10. The method of claim 1, wherein the non-electrophysiological cardiac source information comprises transthoracic impedance information.

11. The method of claim 1, wherein verifying that the separated signal is the cardiac signal comprises providing a detection window within which the cardiac signal is correlated to a signal associated with the non-electrophysiological cardiac source.

12. The method of claim 1, further comprising determining a time separation between a peak of the separated signal and a peak of a signal associated with the non-electrophysiological cardiac source.

13. The method of claim 12, wherein the time separation is used to identify a cardiac signal.

14. The method of claim 1, wherein the signal is separated from the composite electrical signal using blind source separation.

15. The method of claim 14, wherein the blind source separation comprises an independent component analysis performed on the composite electrical signal.

16. The method of claim 1, further comprising detecting a cardiac condition using the separated signal.

17. The method of claim 1, further comprising detecting a cardiac condition using the separated signal by performing a correlation between the separated signal and a signal associated with the non-electrophysiological cardiac source.

18. The method of claim 1, further comprising detecting a cardiac arrhythmia using the cardiac signal.

19. The method of claim 18, further comprising treating the cardiac arrhythmia.

20-29. (Canceled)

30. An implantable device, comprising:

means for subcutaneously detecting a composite electrical signal associated with a plurality of signal sources;

means for subcutaneously detecting non-electrical cardiac activity;

means for separating a signal from the composite electrical signal using source separation; and

means for determining whether or not the separated signal is a cardiac electrical signal using the detected non-electrical cardiac activity.

31. The device of claim 30, wherein the determining means comprises means for performing a time correlation between the separated signal and a signal associated with the detected non-electrical cardiac activity.

32. The device of claim 30, wherein the determining means comprises means for evaluating the separated signal within a detection window.

33. The device of claim 32, further comprising means for determining a start time to initiate the detection window.

34. The device of claim 30, further comprising means for detecting an arrhythmia using the cardiac electrical signal.

35. The device of claim 34, further comprising means for treating the arrhythmia.

36. The device of claim 30, further comprising means for discriminating cardiac rhythms.

37-48. (Canceled)

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.